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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,912	01/30/2004	Carl Ernest Alexander	4506-1025	2239
<div>465 7590 10/02/2009</div> <div>YOUNG & THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314</div>				
EXAMINER				
ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
10/02/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/766,912

Applicant(s)

ALEXANDER ET AL.

Examiner

LEZAH W. ROBERTS

Art Unit

1612

Period for Reply
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 7, 8, 10, 11, 13 and 23-33 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11, 18, 29 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 7, 8, 13, 23-28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments in the Request for Continued Examination, filed July 13, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election by Original Presentation

Newly submitted claim 29 is withdrawn from consideration because it is directed to a non elected species of a skin composition. Applicant elected an oral composition in the response mailed October 23, 2007.

Claims

Claim Rejections - 35 USC § 112 – New Matter (New Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 7, 8, 13, 23-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation "the gel framework configured to break". The limitation "the gel framework configured" does not appear to be disclosed in the originally filed claims or specification. Therefore it is New Matter.

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 7, 8, 13, 23-28 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 4, 7, 8, 13, 23-28 and 30 recite "the gel framework configured to break". It cannot be determined from the instant claims how "the gel framework" is "configured" to break. The term "configured" implies some type of structural arrangement, e.g., a configuration of mechanical parts in a device. It is not seen how configured has any meaning in the context of a claim drawn to a composition, which would not constitute parts to be so arranged.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 1, 3, 4, 7, 8, 13, 23-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 5,354,551 already of record) in view of Alexander

(WO 2002/026078, English Equivalent 2004/0091431 already of record) and Grossmith (GB 750,126 already of record).

Schmidt disclose oral care films comprising tensides, polishing agents, aromatizing agents as well as additional additives which are formulated in a binding agent or mixture of binding agents consisting of water-soluble or water-swellaable, physiologically acceptable film-forming agents. The films are pre-segmented into dosage units (Abstract). The film-forming agents include gelatins, glycerols, natural and synthetic resins and gums (col. 2, lines 28-45). The composition may comprise more than one film former. Liquid components include glycerol and other components include titanium dioxide (a pigment, Example). Actives include menthol, encompassing claim 13. Through the insertion into the mouth cavity and in connection with the saliva and the intensive movement of the toothbrush the strip is pre-dissolved and dissolved so that the components can develop their full activity (col. 3, lines 5-10), encompassing the limitation that the bead is disrupted by a person. The devices may have designs particularly for children (col. 3, lines 13-17).

The reference differs from the instant claims insofar as it does not disclose the compositions are beads, comprise agar or that one bead weighs one gram.

Alexander discloses dental hygiene systems attractive to children, based on a free-flow toothpaste composition in the form of beads. The novel toothpaste makes a substantial contribution to reduction of environmental waste (no waste tubes) and allows the manufacture and distribution of single-unit kits for oral and especially dental hygiene (Abstract). Each bead is colored, flavored and shaped to appeal to a child. The beads

are coated with a gelatin or starch capsule (paragraph 0017). The size of the bead is preferably adjusted so that one bead is sufficient for one tooth brushing procedure (paragraph 0059). Usual toothpaste components include mineral abrasives, a detergent and a flavoring agent (paragraph 0063), encompassing claim 13. The toothpaste is released from the bead when the pressure is applied by the teeth, finger or the bristles on the toothbrush (paragraph 0064). The capsule is disposed (paragraph 0072).

The reference differs from the instant claims insofar as it does not disclose the beads are gel beads that do not comprise a coating.

It would have been obvious to one of ordinary skill in the art to have formulated bead shapes and added colors to the compositions of the primary reference motivated by the desire to make the composition more attractive to children and to promote dental hygiene to children, as disclosed by the secondary reference.

It would also have been obvious to use the film formulation to make the beads of the secondary reference motivated by the desire to use compositions that are physiologically acceptable and do not require disposal of an outer capsule layer, as disclosed by the primary reference.

The references differ from the instant claims insofar as they do not disclose the film forming agents include agar or carrageenan.

Grossmith discloses the production of jellies or viscous solutions. The compositions comprise mixtures of at least two carbohydrate complexes chosen from agar, carrageenan, carboxymethyl cellulose and gum tragacanth. The composition may be used as vehicles for medicaments and other purposes (page 1, col. 1, lines 10-28).

They may also be used as stabilizers for toothpastes and thickeners and /or gelling agents (page 3, col. 1, lines 25-45). The concentration of the carbohydrates, such as agar, determines the structure of the jelly formed (page 1, col. 1, lines 39-46). The strength of the gel also depends on the temperature of mixing (page 2, col. 1, lines 1-5). The concentration of agar ranges from 0.7% to 0.86% of the compositions and carrageenan comprises 1.8% of the compositions (see Examples). The compositions have strong gelling power, create a strong gel with good suspending power and temperature stability; and have a low solid content with strong structure.

The reference differs from the instant claims insofar as it does not disclose the compositions are formulated into single-dose beads as an oral or dental composition.

It would have been obvious to one of ordinary skill in the art to have used agar or carrageenan as the gel forming agents in the compositions of the combined teachings of Schmidt and Alexander motivated by the desire to make single dose gel beads having good strength with good suspending power and temperature stability; and low solid content with strong structure as disclosed by Grossmith.

The combined references do not disclose the mass of the single dose bead of 0.5 to 2.0 grams and does not disclose the amount of gelatin as recited in claim 26. Alexander does disclose the size of the bead is preferably adjusted so that one bead is sufficient for one tooth brushing procedure (paragraph 0059). The size of the bead will determine the amount of active agent that is delivered in a single dose and the amount of gelatin will determine the gelling properties of the compositions. It would take no more than relative skill of one of ordinary skill in the art to determine the size of the bead

to obtain the desired dose to deliver to a user and the amount of gelatin needed to obtain the desired film properties. Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. See MPEP 2144.05. It would have been obvious to one of ordinary skill in the art to have made the bead a certain size and mass, as well as adjusted the amount of gelatin as recited in claim 26, motivated by the desire to deliver an effective amount of the composition to the oral cavity in a suitable size to use comfortably in the oral cavity and to obtain a composition with the desired gel properties, as supported by cited precedent.

Obvious-Type Double Patenting (New Rejection)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 4, 7, 8, 13, 23-28 and 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 17 of copending Application No. 12/067817. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are coextensive insofar as they both encompass a semi-solid gel in the form of a bead or bolus comprising an active agent and agar, which may be used orally. The instant claims differ from the copending claims insofar as they do not recite the hardness of the beads, include the weight of each bead and have the same range for the amount of agar used.

The copending claims do not disclose the exact claimed values for the amount of agar as recited in the instant claims, 0.5 to 1.2%, but do overlap reciting 0.1 to 10%: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). It would have been obvious to one of ordinary skill in the art to have used the compositions of the instant claims to deliver the actives of copending claims motivated by the desire to use a semi-solid gel with the same component, agar, incorporated in overlapping amounts, as supported by cited precedent.

In regards to the hardness, the compositions of the copending claims have the substantially the same components, agar, as the compositions of the instant claims in overlapping amount. Thus, it would be reasonable to conclude that when the amount of agar used is the same, the compositions of instant claims will have the same hardness as the compositions of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3, 4, 7, 8, 13, 23-28 and 30 are rejected.

Claims 10, 11, 18, 29 and 31-33 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612